A Brief Overview of **Individual Case Safety Report Ballot – HL7**

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The Ballot

- Who - The RCRIM Technical Committee's proposal for the Public Health Domain
- What – A model (RMIM & HMD) to support messaging related to reporting of Adverse Events, to support FDA and ICH (E2BM)

Major Items in the Model

- Investigation
- Reaction
- Affected Person
- Drug/Device
- Supporting Clinical Information

Investigation

- Represents investigation of a reaction and pulls together the information from other items in the model
- Associations
  - Primary Source Document(s)
  - Case Seriousness
  - Literature Reference (s)
  - Product (s)
  - Intervention (s)
  - Triggering Reaction (s)
  - Secondary Case Notification (s)
  - Related AE Investigation (s)
  - Author (s)

Reaction

- “Reaction is the consequence of an Adverse Event”
- Associations
  - Supporting Intervention(s)
  - Intervention relatedness
  - Severity
  - Outcome(s)
  - Interpretation(s)
  - Location(s)
  - Concurrent Observation(s)
  - Patient
  - Primary Source Report

Affected Person

- Person(s) affected by reaction.
- Roles
  - Subject
  - Patient
  - Relation

Drug/Device

- The interventions that led to reactions or adverse events
- Two categories
  - Substance administrations (drugs)
  - Procedures (devices)

Supporting Clinical Information

- Relevant clinical or contextual facts including observations from patient's medical history

Comments

- Early version
  - Redundancies
  - Ambiguities
  - Flaws
- Risk
  - A reporting specific model
    - May become incompatible with the domain information model
    - May influence the domain model rather than itself being based on the domain model (wagging the dog!)
    - May be difficult to use for anything besides reporting/documentation
- Opportunity
  - Driver for creating a domain model
  - Comprehensive record of the information requirements